REMARKS

Prior to entry of the present amendment, claims 2, 5-7, 10, 11, 13-21, 23-25, and 30-34 are pending. Claims 2, 10, 11, 16-19, 23-25, 30, 31, and 34 are rejected under 35 U.S.C. § 102. Claims 2, 5-7, 10, 11, 13-21, 23-25, and 30-34 are rejected under 35 U.S.C. § 103. Claims 2, 6, 7, 1, 11, 13-21, 23-25, and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting. Applicants address each basis for rejection as follows.

Claim amendments

Claim 2 has been amended to recite that the "Sendai virus vector" is of a "Sendai virus Z strain." The Sendai virus "Z strain" is described in Figure 1 of Kato et al. (Genes Cells 1: 569-579, 1996; "Kato;" copy submitted with the Information Disclosure Statement filed on April 14, 2010), which is cited in the present specification (at page 27, lines 17-18, page 29, lines 14-15, 19-20, and 27-28, page 30, lines 12-13, and page 32, line 36, to page 33, line 1, of the English language specification). The specification states that "[a]ll publications cited herein are incorporated as a part of the specification" (page 44, lines 11-12).

Moreover, all of the Sendai virus vectors used in Examples of the present specification are derived from Sendai virus Z strain. In particular, the present specification refers to "WO 00/70070" in the description of the Sendai virus vector construction (page 45, line 4, of the English language specification). WO 00/70070, in turn, refers to Kato as describing Sendai virus vector construction. As such, the Sendai virus vectors used in the Examples of the present specification clearly are derived from the Z strain. Claim 2 therefore has been amended to be directed to a vector of the Sendai virus strain used in Examples. Applicants submit that the amendment to claim 2 does not introduce new matter.

In view of the amendment to claim 2, claim 20 has also been amended. Claims 11,

13, 14, 16-19, 21, 23, and 24 have been cancelled. No new matter has been added by these amendments.

Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

Rejections under 35 U.S.C. § 102

Claims 2, 10-11, 19, 23-25, 30, 31, and 34 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gary-Gouy et al. (J. Interferon and Cytokine Res. 22:653-659, 2002; "Gary-Gouy"). Claims 11, 16-19, and 24 are rejected under 35 U.S.C. § 102(e) as being anticipated by Pickles et al. (US 2005/0048030; "Pickles").

As noted above, claim 2 and its dependent claims are directed to a Sendai virus vector of a "Sendai virus Z strain." Applicants submit that neither Gary-Gouy nor Pickles describes use of a Sendai virus Z strain. As the cited art fails to describe each and every element of the claimed invention, neither Gary-Gouy nor Pickles can anticipate the claims as amended. Applicants submit that the anticipation rejection over Gary-Gouy or Pickles may be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 2, 5-7, 10-11, 13-21, 23-25, and 30-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Song et al. (US 2002/0123479 A1; "Song") in view of Tokusumi et al. (US 6,746,860; "Tokusumi"), Jin et al. (Gene Therapy 10:272-277, 2003; "Jin"), Hwu et al. (US 6,734,014; "Hwu"), and Waller et al. (US 2005/0013810; "Waller"). The Office also cites Lopez et al. (JID 187:1126-1136, 2003; "Lopez") in support of the assertion that "at the effective filing date of the present application, it was already known in the prior art ... that Sendai viruses (live or inactivated) can induce maturation of infected immature dendritic cells" (Office Action at page 23). Applicants respectfully submit that the claims as amended are nonobvious over the cited art.

As noted above, the amended claims are directed to use of a Sendai virus vector of a Sendai virus Z strain in methods for producing a mature dendritic cell. None of the cited references describes use of a vector of a Sendai virus Z strain and, as explained below, the cited references fail to teach or suggest that such a vector could be used to successfully produce mature dendritic cells.

Lopez states (page 1129, left column; emphasis added):

> Influenza delNS 1 and Sendai Cantell viruses, the high IFN [interferon] inducers, triggered higher levels of expression of costimulatory molecules (figure 1) and cytokines (table 2) than their low IFN-inducing counterparts influenza PRS and Sendai 52 viruses. It is notable that the influenza viruses are weaker inducers of cytokine secretion from DCs [dendritic cells] than are the Sendai viruses. These results establish a correlation between type I IFN production by DCs after viral infection and the induction of DC maturation.

Accordingly, while Sendai Cantell virus is a potent inducer of IFN-I, Sendai 52 virus is a very poor inducer of IFN-I and the expression levels of costimulatory molecules were also lower comparing with the high IFN inducers such as Influenza delNS 1 and Sendai Cantell viruses (Fig. 1 of Lopez). As co-stimulatory molecules such as CD80 and CD86 are known as maturation markers (see page 1126, left column, last 3 lines of Lopez), the results indicate that Sendai 52 virus poorly induces the maturation of DCs. Based on these results, Lopez concluded that "[t]hese results establish a correlation between type I IFN production by DCs after viral infection and the induction of DC maturation" (as cited above).

The Office appears to follow Lopez's conclusion and states that "[i]mportantly, Lopez demonstrated that while the Sendai Cantell virus is a very potent inducer of IFN in immature dendritic cells, the Sendai 52 is a very poor inducer of this pathway (see at least the section entitled "Type I IFN secretion by DCs infected with influenza or Sendai viruses" on page 1128 and Table 1)" (Office Action at page 17, lines 5-8 from the bottom, and page 21, lines 9-13; emphasis added), and further states that Lopez "already

taught that ... a strong correlation exists between murine DC maturation and the induction of IFN" (Office Action at page 6, lines 10-11; emphasis added).

Gary-Gouy uses another Sendai virus (Sendai virus E72 strain; see page 654, right column, line 6). As the Office states in the current Office Action (page 3, lines 5-6 from the bottom; and page 5, lines 10-11), Gary-Gouy, on page 655, states that "[m]onocytes and CD123hi PDC but not CD11c+ MDC produce IFN-1 on specific stimulation" (emphasis added). The Office further acknowledges that the Sendai virus infection resulted in "the very low observed induced level of IFN-I" (page 17, line 5, of the Office Action; emphasis added), and that "MDC cells infected with Sendai virus were shown to produce IFN-1 even though the induced level is very little (see at least Table 1)" (page 17, line 9-10, emphasis added).

Considering that Lopez "already taught that ... a strong correlation exists between murine DC maturation and the induction of IFN" (page 6, lines 10-11, of the Office Action; emphasis added), Applicants submit that, in accordance with this reasoning, Sendai virus E72 used in Gary-Gouy, which induced IFN-1 at very low level, is also a poor inducer of DC maturation. As such, the art describes two Sendai virus strains, 52 and E72, which are poor inducers of DC maturation. In sum, only Sendai virus Cantell was known to induce potent DC maturation, and other Sendai viruses, such as strains 52 and E72 were known to poorly induce DC maturation.

In contrast, Sendai virus Z strain used in Examples of the present specification is a potent inducer of DC maturation, as evidenced by the expression of co-stimulatory molecules (maturation markers) such as CD80 and CD86 which were highly induced (see, e.g., Figures 12, 14, 15, and 20 of the specification). Applicants submit that nothing in the cited references would lead one skilled in the art to use a Sendai virus vector of a Sendai virus Z strain in a method for producing a mature DC, much less have a reasonable expectation that such a method would be successful.

Applicants submit that the presently claimed invention is directed to the

unexpected result, supported by the Examples of the application as filed, that a Sendai virus Z strain vector is a potent inducer of DC maturation. These results support Applicants' contention that the presently claimed invention is nonobviousness over the cited art where the ability of Sendai virus to induce DC maturation varies between viruses and was unpredictable. Given that the prior art provides "either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful," the claimed invention would not have been obvious. *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 996-97, 90 U.S.P.Q.2d 1947, 1951 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988). The present rejection under 35 U.S.C. § 103 should be withdrawn.

Provisional Nonstatutory Obviousness-Type Double Patenting

Claims 2, 6-7, 10, 11, 13-21, 23-25, and 30-34 are provisionally rejected on the ground on nonstatutory obviousness-type double patenting over claims 2, 3, 7-9, 12, and 15-35 of co-pending application serial number 11/630,532 ("the '532 application").

Applicants again note that the present application, filed May 3, 2006, is the U.S. national stage of a PCT international application filed on October 29, 2004, whereas the '532 application, filed December 21, 2006, is the U.S. national stage of a PCT international application filed on April 28, 2005. Applicants submit that the present application, relative to the '532 application, is the earlier filed application. As such, in accordance with M.P.E.P. § 804, if the provisional obviousness-type double patenting rejection is the last remaining rejection in the present case, Applicants respectfully request that this provisional rejection be withdrawn and the application allowed to issue.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office Action for three (3) months, to and including January 22, 2011, and an authorization to charge the required extension fee to Deposit Account No. 03-2095.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Jan N. Tittel, Ph.D.
Reg. No. 52,290

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045